



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,768	04/12/2002	Kaneyoshi Kato	2651 USOP	2281

7590 02/20/2004

Mark Chao
Takeda Pharmaceuticals North America
Suite 500
475 Half Day Road
Lincolnshire, IL 60069

EXAMINER

LIU, HONG

ART UNIT	PAPER NUMBER
----------	--------------

1624

DATE MAILED: 02/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/088,768	Applicant(s) KATO ET AL.	
	Examiner Hong Liu	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 1-16, 35 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 17-34 and 37 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>03/20/02</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-37 are pending in this application.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-16 and 35-36, drawn to a method of using the compounds.

Group II, claim(s) 17-34 and 37, drawn to the compounds of formula I.

Inventions I and II are related as product and process of use. It is evident that all of the compounds represented by formula I(a) or (Ib) or the formula in claim 37 are, as compounds, included within the compounds represented by the formula in claim 1. However, the results of investigation of the prior art indicate that the descriptions in claims 1-16 and 36 confound the two inventive concepts of "invention of a pharmaceutical application for novel compounds" and "invention of novel pharmaceutical application for known compound." As a result, the inventions described in claims 1-16 and 36 and the inventions described in claim 17-34 and 37 are not a group of inventions so linked as to form a single general inventive concept.

2. During a telephone conversation with Mr. Mark Chao on 02/13/04 a provisional election was made with traverse to prosecute the invention of Group II, claims 17-34 and 37. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-16, 35 and

Art Unit: 1624

36 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17, 23, and 29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The scope of “prodrug” is not adequately enabled. Applicants provide no guidance as how the compounds are made more active in vivo. The choice of a “prodrug” will vary from drug to drug. Therefore, more than minimal routine experimentation would be required to determine which prodrug will be suitable for the instant invention.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23, 25, 27, and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

1) In claims 23, 25, and 30, the phrase “optionally having substituents” is unclear as to the nature and number of substituent(s) intended.

Art Unit: 1624

2). Claim 27 is rejected for failing to comply with 37 CFR 1.141(a), which is said by In re Fressola to have the force of law, 22 USPQ 2d 1828. There is no generic concept for the claim. The claim lists more than a reasonable number of species, and thus, is an aggravated, multiple page, example of listing ultimate species in one claim to avoid fees.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 17-34 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kato et al. (WO 97/244325). Kato et al. teach a generic group of diphenylmethane derivatives (See formula I, p. 3) wherein ring N-Z is a substituted monocyclic nitrogen-containing heterocyclic group, R1 can be a substituted lower alkyl-carbonyl group etc. (See examples No. 1-39). Compound 9 of Kato, on page 166 differs from the compounds in claim 17 only in nature of R23 which is alkyl having alkoxy-carbonylamino rather than alkyl having aralkyloxy-carbonylamino. Compound 12 on page 168 differs from the compounds in claim 23 only in nature of R29 which is alkyl rather than aryl or heteroaryl. However, the compounds of the instant invention are generically embraced by Kato in view of the equivalence of alkyl, aryl, or aromatic heterocycle, etc.,. Thus, one of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus. See In re Susi, 440

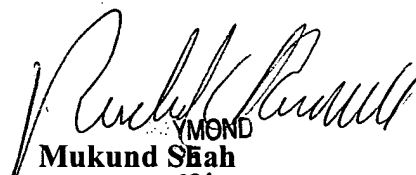
Art Unit: 1624

F.2d 442, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in *Merck & Co. V. Biocraft Laboratories*, 847 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

Any inquiry concerning this communication should be directed to Examiner Hong Liu whose telephone number is (571) 272-0669. The examiner can normally be reached on Monday through Friday from 8:30 AM to 6:00 PM.

If attempts to reach the examiner by the phone are unsuccessful, the examiner's supervisors, Mukund Shah or James Wilson can be reached at (571) 272-0674 or (571) 272-0661, respectively. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 358-1235.


Mukund Shah
Supervisory Patent Examiner
Art Unit 1624

hl
February 16, 2004